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Original Article

Effectiveness of Ventricular Intrinsic Preference (VIP™) and Ventricular AutoCapture (VAC) algorithms in pacemaker patients: Results of the validate study



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ABSTRACT

Background: Several past clinical studies have demonstrated that frequent and unnecessary right ventricular pacing in patients with sick sinus syndrome and compromised atrio-ventricular conduction (AVC) produces long-term adverse effects. The safety and efficacy of two pacemaker algorithms, Ventricular Intrinsic Preference™ (VIP) and Ventricular AutoCapture (VAC), were evaluated in a multi-center study in pacemaker patients.

Methods: We evaluated 80 patients across 10 centers in India. Patients were enrolled within 15 days of dual chamber pacemaker (DDDR) implantation, and within 45 days thereafter were classified to either a compromised AVC (cAVC) arm or an intact AVC (iAVC) arm based on intrinsic paced/sensed (AV/PV) delays. In each arm, patients were then randomized (1:1) into the following groups: VIP OFF and VAC OFF (Control group; CG), or VIP ON and VAC ON (Treatment Group; TG). Subsequently, the AV/PV delays in the CG groups were mandatorily programmed at 180/150 ms, and to up to 350 ms in the TG groups. The percentage of right ventricular pacing (%RVp) evaluated at 12-month post-implantation follow-ups were compared between the two groups in each arm. Additionally, in-clinic time required for collecting device data was compared between patients programmed with the automated AutoCapture algorithm activated (VAC ON) vs. the manually programmed method (VAC OFF).

Results: Patients randomized to the TG with the VIP algorithm activated exhibited a significantly lower %RVp at 12 months than those in the CG in both the cAVC arm ($39 \pm 41\%$ vs. $97 \pm 3\%$; $p=0.0004$) and the iAVC arm ($15 \pm 25\%$ vs. $68 \pm 39\%$; $p=0.0067$). In-clinic time required to collect device data was less in patients with the VAC algorithm activated. No device-related adverse events were reported during the year-long study period.

Conclusions: In our study cohort, the use of the VIP algorithm significantly reduced the %RVp, while the VAC algorithm reduced in-clinic time needed to collect device data.

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1. Introduction

Several clinical studies (Danish I [1,2] Danish II [3,4] DAVID [5], MOST sub-analysis [6], MADIT II Substudy [7,8]) have demonstrated that frequent and unnecessary pacemaker right ventricular pacing (RVp) in patients with sinus node disease and atrio-ventricular (AV) block can lead to long-term adverse effects, including atrial fibrillation (AF) and heart failure. Ventricular dyssynchrony caused by

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unnecessary RVp causes valvular regurgitation followed by left atrial enlargement and remodeling, which predisposes patients to AF. In addition, these patients are at a greater risk of developing congestive heart failure due to altered cardiac hemodynamics caused by ventricular dyssynchrony [3,5,6]. One option to reduce the percentage of RVp in patients with sick sinus syndrome (SSS) but with normal AV conduction (AVC) is to establish functional AAIR (NBG code for single-chamber atrial inhibited pacing with rate modulation) pacing by using the DDDR (NBG code for dual chamber pacing with atrial tracking and rate modulation) mode with a long AV delay. However, in patients with diseased intrinsic AV, RVp with excessive AV delays may result in non-physiological AV delays and further deterioration in ventricular hemodynamics [3,9].

Two different pacemaker concepts have evolved to promote intrinsic conduction and pacing with a reasonable AV delay when needed: AV hysteresis algorithms and algorithms based on the AAI/DDD (mode switch. AV hysteresis algorithms essentially work with two different AV delays; a shorter AV delay to provide optimal hemodynamics with ventricular pacing, and a longer AV delay to promote intrinsic conduction. AAI/DDD mode switch-based features do not trigger an AV delay, and therefore allow very long AV delays and pauses of up to 3 s. Clinical data for both strategies are mainly confined to small studies evaluating safety and efficacy, and have demonstrated low ventricular pacing percentages [10,11].

The two algorithms, “Ventricular Intrinsic Preference™ (VIP)” and “Ventricular AutoCapture (VAC)”, represent enhanced features of DDDR pacemakers. The VIP algorithm monitors intrinsic cardiac rhythm and provides pacing when required, thereby activating/deactivating on a beat-by-beat basis. It works upon AV hysteresis, in which the AV delay is varied to a level just longer than the intrinsic AV delay, thereby promoting intrinsic conduction. The VIP algorithm is deactivated when the number of VP events becomes equals to the number of programmed search cycles at the extended AV delay. In contrast, the VAC algorithm senses beats and increases the amplitude [by 1/4 (0.25) V for one beat]. Furthermore, if the capture is confirmed, the pacemaker delivers the same amplitude again to re-confirm the capture. After the capture is confirmed, a threshold search is initiated. During the search, the pulse amplitude is decreased by 1/4 (0.25) V two beats at a time until the capture is lost for two consecutive beats. The pulse amplitude is then increased by 1/8 (0.125) V-increments until two consecutive captured beats are present (this is known as the “capture threshold”). The amplitude is then set 1/4 (0.25) V above the threshold and established a working safety margin.

In the present study (Evaluation of Ventricular Intrinsic Preference Plus Ventricular AutoCapture Features in Dual Chamber Pacemaker PaTiEnts-VALIDATE), we evaluated the effects of the VIP algorithm in the management of dual chamber pacemaker patients. Additionally, the impact of the VAC algorithm on in-clinic time was evaluated at 6 and 12 months.

2. Material and methods

This was a prospective, randomized, single-blinded, multicenter study conducted at 10 centers in India. Prior to patient enrollment, appropriate institutional review board approval for the protocol, patient information sheets, and consent forms was obtained. The study was conducted in accordance with the Declaration of Helsinki, ISO 14155, and all local requirements including registration on the public domain Clinical Trials Registry of India (www.ctri.nic.in; reference number: CTRI/2010/091/000179) before the 1st patient was enrolled. The study protocol was approved by the Institutional Ethics Committee (from May, 2010 to March 2011) of all centers concerned prior to the initiation of the study at their respective sites.

2.1. Patient selection

From July 2010 to July 2011 consecutive patients who had an indication for dual chamber pacemaker implantation according to the ACC/AHA/HRS guidelines and who were geographically stable, willing to provide written informed consent, and complied with the required follow up schedule were invited to participate in the study. Patients with permanent AV block, persistent or permanent AF/atrial flutter (AFL), pacemaker replacement, New York Heart Association classification (NYHA) class IV, current pregnancy, age < 18 years, and life expectancy < 12 months were excluded from the study.

In order to standardize the device-based diagnostics used to evaluate study endpoints, only patients with either a Zephyr DR 5820 model or Zephyr XL DR 5826 model implant manufactured by St. Jude Medical, Inc. were invited to participate in the study (within 15 d of pacemaker implantation). After obtaining informed consent, patients' demographic data regarding age, weight, height, gender, NYHA class, and blood pressure were recorded. Additionally, relevant patient data on pacemaker implant indications (rhythm/conduction disorder), right atrium and right ventricle lead position (chest X-ray), medical history including atrial tachyarrhythmia (AF/AFL), 12 lead electrocardiograms (ECGs), echocardiography (left ventricle ejection fraction [LVEF]), and ongoing cardiovascular medication were collected.

2.2. Device characteristics

The device was inspected post-implantation, which included real-time measurements of atrial and ventricular pacing, sensing thresholds, and lead impedance. An over-sensing test was performed to optimize the device's sensing performance to ensure that there was no ventricular signal detected on the atrial channel. The pacemakers were programmed to the DDD(R) mode with a base rate of ≤ 60 bpm and with the paced/sensed AV delay set at 180/150 ms (Table 1).

2.3. Randomization

Within 45 d post-implantation, patients returned for a randomization visit, during which the patient's data regarding NYHA class, blood pressure, 12 lead ECG, ongoing cardiovascular medications, and adverse events (AEs) were collected.

Based on an AVC test, all enrolled patients were stratified to either the compromised AVC (cAVC) arm or the intact AVC (iAVC) arm. This was performed based on the intrinsic paced/sensed (AV/PV) delay (if measurable) and the results of AVC testing. Patients with an AV/PV delay > 210 ms or with no intrinsic conduction on surface ECG were placed in the cAVC arm while patients with an AV/PV delay ≤ 210 ms were further evaluated during an AVC test to ensure 1:1 AVC during temporary atrial pacing. The test was started at a sinus rate of +10 bpm and was then increased by increments of 10 bpm until either 120 bpm was reached or Wenckebach behavior was observed. Patients in whom 1:1 AV conduction was lost during the test were randomized to the cAVC arm, while all other patients were randomized to the iAVC arm, unless patients in whom the ventricular R wave interval was ≥ 350 ms, or with ventricular pacing at any time during the AVC test.

Furthermore, each arm was classified into a Control group (CG: VIP OFF + VAC OFF) and a Treatment group (TG: VIP ON + VAC ON) at a 1:1 ratio using stratified permuted block randomization.

In the TG, both VIP and VAC were activated. AV delay prolongation was set at 350 ms with the search cycle and search interval set to 3 and 30 s, respectively. As VAC provides flexibility with Beat-by-Beat™ capture verification, an autocapture setup test was performed to ensure that VAC could be activated in each patient.

Table 1
Baseline device programming.

Basic parameters		
Mode	DDD(R)	
Base rate	≤ 60	
Max track rate	220-Age*0.8 or 0.9	
Paced AV delay	180 ms	
Sensed AV delay	150 ms	
Rate responsive AV/PV delay	OFF	
Atrial refractory (PVARP)	275 ms	
RR PVARP	Medium	
Atrial sensitivity	0.3 mV	
<i>Extended parameters</i>		
Auto mode switch	DDI (R)	
Atrial tachycardia detection rate	20 bpm above max tracking rate or 180 bpm	
AF Suppression™	OFF	
Post Vent. Atrial Blanking	Optimized (Oversensing test)	
PMT options	Autodetect	
<i>Stored EGMs parameters</i>		
Sampling options	Continuous	
No. of stored EGMs	8	
Maximum duration	6 s	
Channel	Dual	
Atrial EGM configuration	A.Bipolar	
Atrial dynamic range	± 3.0 mV	
Vent. EGM configuration	V.Bipolar	
Vent. dynamic range	± 15.0 mV	
PMT detection	ON	
High ventricular rate	ON (175 bpm)	
Number of consecutive cycles	10	
AT/AF detection	ON	
<i>Additional parameters (randomization)</i>		
VIP™	CG	TG
Prolongation	N/A	Open
Search cycles	N/A	30 s
Search interval	N/A	3
Ventricular autocapture	OFF	ON

AV – Atrio-ventricular, AF – atrial fibrillation, AT – atrial tachycardia, CG – Control group, EGM – Electrogram, N/A – Not applicable, PV – Paced delay, PMT – Pacemaker mediated tachycardia, VIP – Ventricular Intrinsic Preference algorithm, TG – Treatment Group.

Pacemaker investigation similar to that performed at the baseline visit was performed. The in-clinic time required to measure the ventricular capture threshold using a manual decrement test was noted. Subsequently, the time for updating the threshold values by VAC algorithm were noted to be automated. A comparison between the two (manual and automated) was carried out. When an automated value was observed to be more than the manual value by 0.25, it was determined to be 100% accuracy.

All patients were followed-up at 3, 6, and 12 months post-implantation and the tests performed at the randomization visit were repeated, except the AVC test, which was not performed at the 3 month follow-up visit.

2.4. Sample size calculation

The sample size estimation was based on the primary endpoint and study design, comparing %RVp at 12 months between the VIP ON+VAC ON group (TG) and the VIP OFF+VAC OFF group (CG) for the patients with compromised AVC, as well as for patients with intact AVC. The %RVps reported in the cAVC arm of a previous study [12] were 32 ± 36 and 82 ± 29 for TG and CG, respectively, while those in the iAVC arm were 12 ± 26 and 58 ± 37 for the TG and CG, respectively. In order to detect similar difference in %RVp between the TG and CG in the present study, at least 11 patients from each group were required in the cAVC arm and at least 12 patients from each group were required in the iAVC arm to maintain a joint power of 90% and a significance level of 5%. With a dropout rate of 15% every 6 months, 80 patients needed to be recruited in total (Fig. 1).

2.5. Statistical methods

The primary endpoint was summarized using descriptive statistics (mean, standard deviations, medians, ranges) and comparisons between the groups were performed using the unpaired *t*-test when data were normally distributed. When data were not normally distributed, the equivalent nonparametric test (Wilcoxon rank sum test) was used. Data were checked for normality using box plots, normal quartile plots, and normality tests. Comparisons

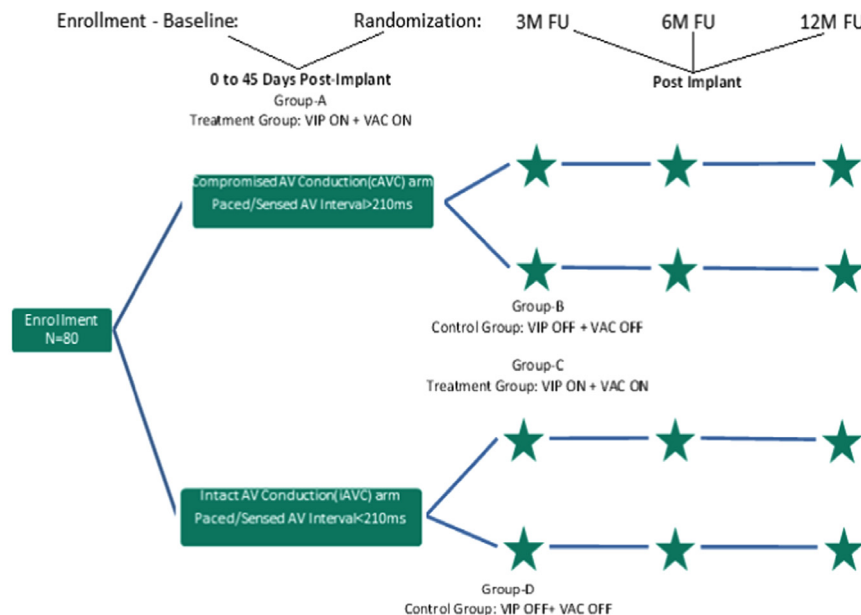


Fig. 1. Study flow chart. The figure depicts study flow chart. It illustrates the study design, according to which the patients based on their intrinsic Atrio-ventricular conduction were divided into either Compromised AV Conduction arm or Intact AV Conduction arm. In both arms patient were then randomized to VIP ON+VAC ON group (TG) and VIP OFF+VAC OFF group (CG).

Table 2
Baseline demographic data.

Patient's characteristics	Randomized group					
	cAVC		p-Value	iAVC		p-Value
	CG N=22	TG N=25		CG N=15	TG N=16	
Gender (n/%)	7/31	6/24	0.55	7/46	5/31	0.38
Female						
Age (years)[€]	65 ± 12	66 ± 13	0.70	63 ± 9	65 ± 11	0.56
Mean ± SD						
Height (cm)[€]	162 ± 8	163 ± 8		162 ± 13	162 ± 9	
Mean ± SD						
Weight (kg)	65 ± 16	61 ± 10		66 ± 16	57 ± 9	
Mean ± SD						
Systolic blood pressure (Hg)	129 ± 17	123 ± 16	0.23	125 ± 17	121 ± 17	0.47
Mean ± SD						
Diastolic blood pressure (Hg)	74 ± 7	72 ± 11	0.48	74 ± 11	74 ± 8	0.92
Mean ± SD						
LVEF (%)[¥]	54 ± 13	52 ± 8	0.66	58 ± 7	58 ± 8	0.80
Mean ± SD						
LVESD (mm)[¥]	25 ± 5	30 ± 5	0.07	27 ± 6	29 ± 5	0.29
Mean ± SD						
LVEDD (mm)[¥]	40 ± 3	47 ± 4	0.23	37 ± 9	42 ± 2	0.61
Mean ± SD						
Pacemaker implant indication (n/%)[¶]						
Sick sinus syndrome	7/31	17/68		5/33	10/62	
Sinus bradycardia	4/18	13/52		4/26	6/37	
SA block/sinus arrest	3/13	5/20		1/6	5/31	
Intermittent AV-block	14/63	6/24		8/53	6/37	
NYHA class (n/%)						
I	13/59	14/56		8/53	12/75	
II	9/40	6/24		6/40	2/12	
III	0/0	3/12		1/6	2/12	
Unknown	0/0	2/8	0.21	0/0	0/0	0.31
P value						
Medical history (n/%)						
None	3/13	4/16		0/0	5/31	
Hypertension	14/63	16/64		8/53	7/43	
CAD	6/27	7/28		5/33	3/18	
HCM	0/0	1/4		0/0	0/0	
TIA/RIND/CVA/stroke	0/0	1/4		0/0	0/0	
MI	1/4	1/4		2/13	1/6	
Diabetes mellitus	7/31	9/36		7/46	3/18	
Renal insufficiency	1/4	0/0		0/0	0/0	
Valve disease	0/0	1/4		0/0	0/0	
Cardiac surgery	3/13	5/20		2/13	2/12	
Other	7/31	6/24		6/40	5/31	
Medication						
ACE-inhibitors/ARB	11	11		7	6	
Amiodarone	0	1		1	3	
Anticoagulant	3	6		3	1	
Anti-platelets	5	9		3	5	
Beta-blocker	3	6		3	5	

AV – Atrio-ventricular, ACE – Angiotensin converting enzyme, ARB – Angiotensin receptor blocker, cAVC – Compromised Atrio-ventricular conduction, CAD – Coronary artery disease, CVA – Cerebrovascular accident, CG – Control group, HCM – Hypertrophic cardiomyopathy, iAVC – Intact Atrio-ventricular conduction, LVEF – Left ventricular ejection fraction, LVESD – Left ventricular end systolic diameter, LVEDD – Left ventricular end diastolic diameter, MI – Myocardial ischemia, N – Number, NYHA – New York Heart association, RIND – Reversible Ischemic Neurologic Deficit, SA – Sino-atrial, SD – Standard Deviation, TG – Treatment Group, TIA – Transient ischemic attack.

[€] Age was calculated by subtracting the date of the baseline visit with the date of birth divided by 365.25 (because of the leap years).

[¶] Baseline data not available for 1 patient in the AVC VIP ON+VAC ON

Group.

[¥] Echo data is not available for all patients as it was not mandatory protocol requirement.

[¶] Multiple choices may have been checked for each patient.

were expressed in *p*-values, and the null hypothesis was rejected if the *p*-value was less than 0.05. All continuous variables are expressed as mean ± standard deviations. All categorical data were presented using frequencies and percentages.

3. Results

3.1. Study population

A total of 80 patients were recruited at 10 centers in India. Seventy-eight of these patients were randomized (two patients withdrew their consent prior to randomization visit due to non-study related reasons). Seventy-one patients completed the 12 month follow-up period. Data for seven patients were not available as there were four deaths and four losses to follow-up. Thirty-seven patients were randomized to the CG and forty one to the TG.

The baseline characteristics, such as age, height, weight, diastolic/systolic blood pressure, LVEF, NYHA class, medical history, and medication are described in Table 2.

Post-implantation, 12-lead ECGs were reviewed by physicians for cardiac rhythm, which showed that in the cAVC arm, seven patients had sensed AV, 21 had sensed atrial and paced ventricle, seven had paced atrial and sensed ventricle, and none had paced AV. In contrast, in the iAVC arm, 10 patients had sensed AV, 13 had sensed atrial and paced ventricle, six had paced atrium and sensed ventricle, and only one had paced AV.

Activating VIP resulted in a significant reduction of %RVp after 12 months in both the cAVC and iAVC arms. In the iAVC arm, VIP reduced the %RVp from 68 ± 39% in the CG to 15 ± 25% in the TG (*p*=0.0067). In the cAVC arm, VIP reduced the %RVp from 97 ± 3% in the CG to 39 ± 41% in TG (*p*=0.0004) (Figs. 2 and 3). The %RVp at the 6-month follow-up visit showed much lower percentages than at the 12-month follow-up visit (Table 3).

3.2. Manual in-clinic time vs. automated in-clinic time in the treatment group

Within the TG of the cAVC arm, the difference between the manual and automated in-clinic time was 49 ± 34 min, 37 ± 17 min, 32 ± 13 min, and 24 ± 11 min at the randomization visit, 3-month follow-up, 6-month follow-up, and 12-month follow-up, respectively. Similarly, for the TG of the iAVC arm, the difference between the manual and automated in-clinic time was 53 ± 38 min, 41 ± 27 min, 30 ± 7 min, and 31 ± 13 min for the respective visits. This shows that less time was required to retrieve the device measurements in-clinic by the automated method than the manual method (*p* < 0.001 within iAVC and cAVC arms) (Table 4).

3.3. Percentage of VAC accuracy (V) in ventricular pacing threshold measurements (manual vs. automatic methods)

The mean VAC accuracy for the ventricular pacing threshold in the cAVC (TG) and iAVC (TG) arms was 126% (*n*=25) and 100% (*n*=14) at randomization, 99% (*n*=19) and 104% (*n*=14) at the 3-month follow-up, 100% (*n*=20) and 100% (*n*=11) at the 6-month follow-up, and 100% (*n*=22) and 101% (*n*=13) at the 12-month follow-up, respectively (Table 4).

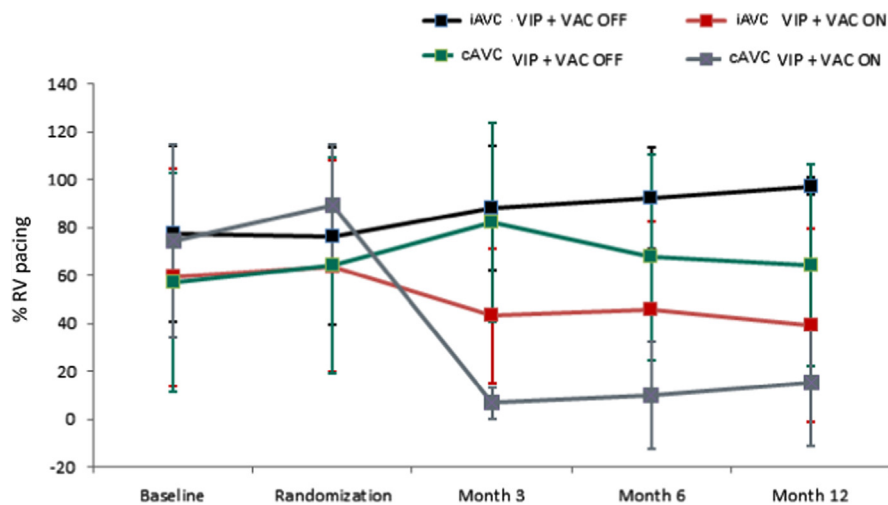


Fig. 2. Mean \pm SD plot of percentage of RV pacing over study period. The figure depicts significant reduction of %RVp at 12-Month follow up when VIP algorithm was activated in both cAVC & iAVC arms. In the iAVC group, %RVp was reduced by VIP from $68 \pm 39\%$ in CG to $15 \pm 25\%$ in TG ($p=0.0067$). In the cAVC group, VIP reduced the %RVp from $97 \pm 3\%$ in CG to $39 \pm 41\%$ in TG ($p=0.0004$).

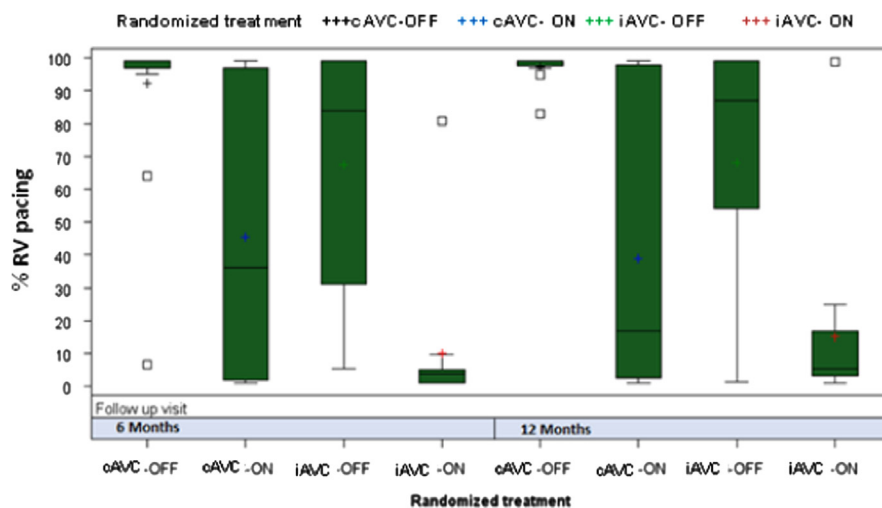


Fig. 3. Box plot for percentage of RV pacing at 6-Month & 12-Month visit. The figure depicts box plot representation for significant reduction of %RVp at 12-Month follow up when VIP algorithm was activated in both cAVC & iAVC arms. In the iAVC group, %RVp was reduced by VIP from $68 \pm 39\%$ in CG to $15 \pm 25\%$ in TG ($p=0.0067$). In the cAVC group, VIP reduced the %RVp from $97 \pm 3\%$ in CG to $39 \pm 41\%$ in TG ($p=0.0004$).

3.4. Adverse events

A total of 18 serious adverse events (SAE) were reported over the course of the study period, including five cardiovascular AEs, four (16%) in patients from the 'cAVC – TG' group, and one in (6%) a patient from the 'iAVC – TG' group. No device-related AEs were reported during the study period. One SAE was reported prior to the randomization visit. In the TG of the cAVC arm, one (4%) death occurred, whereas two deaths occurred in the TG of the iAVC arm (13%). Seven of 25 patients in the TG of the cAVC arm and 1/16 patients in the TG of the iAVC-arm were hospitalized at least once during the course of the study; all of these hospitalizations were found not to be related to the study.

4. Discussion

RVp has been a clinical standard for many decades. Clinical studies conducted in the last decade have highlighted the benefit of reducing RVp in patients who do not require ventricular pacing [13]. Different studies conducted across the world support the view that

frequent RVp may have long term side effects, including an increased risk of developing AF or congestive heart failure [2,6,14].

The VIP Algorithm is based on AV hysteresis, and works by enhancing the promotion of intrinsic conduction [15–17]. The enhanced VAC features an algorithm designed to confirm a response to each and every pacing stimulus, as well as automatically adjust the output in response to changes in the capture threshold, thereby minimizing energy consumption and improving the longevity of the device [14].

A previous study from St. Jude Medical (EVITA) demonstrated that VIP provides allows medium and long term incidence of unnecessary ventricular pacing in patients with intact AV conduction to be reduced. The study also showed that the VIP reduces the percentage of ventricular pacing from 64% with VIP deactivated to 9% with VIP activated [15]. The VIP Study evaluated the efficacy of VIP in reducing unnecessary RVp, and determined whether patients would benefit from using VIP rather than a programmed AV/PV delay only. The VIP algorithm reduced unnecessary RV pacing in pacemaker patients with intact AVC by 81% [18].

We produced results similar to those of previous studies. Activating VIP resulted in a significant reduction in mean %RVp at

Table 3

Six-month and 12-month follow-up visit ventricular pacing for both groups.

Arm	Group	6-month follow-up		12-month follow-up		p-Value
		N	Mean \pm SD	N	Mean \pm SD (%)	
cAVC	CG	21	92 \pm 21	21*	97 \pm 3	0.0004
	TG	23	45 \pm 43	23	39 \pm 41	
iAVC	CG	15	67 \pm 36	13	68 \pm 39	0.0067
	TG	12	9 \pm 22	14	15 \pm 25	

cAVC – Compromised Atrio-ventricular conduction, CG – Control group, iAVC – Intact Atrio-ventricular conduction, N – Number, SD – Standard Deviation, TG – Treatment Group.

* Data not available for one patient.

Table 4

Secondary endpoint analysis.

Visit	Difference between manual and automated in clinic time (min) within treatment groups (TG)*				Individual visit VAC accuracy (V) for treatment group					
	cAVC – TG		iAVC – TG		cAVC – TG			iAVC – TG		
	N	Mean \pm SD	N	Mean \pm SD	N	Mean \pm SD	AVD	N	Mean \pm SD	AVD
Randomization	25	49 \pm 34	15	53 \pm 38	25	0.38 \pm 0.71	0.13 \pm 0.71	14	0.25 \pm 0	0
Month 3	20	37 \pm 17	14	41 \pm 27	19	0.24 \pm 0.03	–0.01 \pm 0.03	14	0.38 \pm 0.47	0.13 \pm 0.47
Month 6	22	32 \pm 13	12	30 \pm 7	22	0.25 \pm 0	0	11	0.25 \pm 0	0
Month 12	22	24 \pm 11	13	31 \pm 13	22	0.25 \pm 0.04	0 \pm 0.04	13	0.26 \pm 0.03	0.01 \pm 0.03

AVD – Absolute value difference, cAVC – Compromised Atrio-ventricular conduction, iAVC – Intact Atrio-ventricular conduction, CG – Control group, N – Number, SD – Standard Deviation, TG – Treatment Group.

* $p < 0.0001$ within iAVC and cAVC group.

12 months in patients with either compromised or intact AVC. At 6 months, %RVp was found to be 45 \pm 43 in the cAVC arm and 9 \pm 22 in the iAVC arm.

The in-clinic time required to retrieve device measurements by automated and manual methods showed that less time was required to retrieve the device measurements via the automated method. A total of 18 AEs were reported, although none was device-related.

As in previous studies [13,19], we showed that keeping VIP activated significantly reduces ventricular pacing in patients with compromised or intact AV conduction, and that this reduction may be sustained over a 12-month period. Of the 23 patients with compromised AVC and pacemaker algorithms activated, only 17% ventricular pacing was observed. This shows that in the TG, intrinsic ventricular conduction was encouraged most of the time.

4.1. Limitations

An overall drop-out rate of 11% was observed during the course of this study. The impact of drop-out rate on the study outcome is unknown, as the overall findings are consistent with previous studies. In our study, AV delay was pre-defined in the protocol, thereby allowing all investigators to make fair assessments. Unlike in many other studies, shorter AV delay was programmed for the control group (DDD/R mode), and (VIP+VAC ON) longer AV delay was programmed for treatment group.

4.2. Programming recommendations

The VIP algorithm should be considered in patients with symptomatic bradycardia including sinus node dysfunction and compromised or intact AVC. VIP maximizes AV synchrony, and thereby reduced unnecessary RV pacing. With the help VAC, all threshold tests can be completed automatically. In addition, intrinsic signals

and lead impedances can be measured automatically, and trend can be analyzed easily. The automated method should be considered, as it can significantly reduce the in-clinic time compared to manual methods of device measurement collection.

5. Conclusion

This study shows that VIP significantly reduces %RVp in patients with compromised as well as intact AVC. Avoiding RVp using algorithms such as VIP will help to reduce cardiovascular events related to unnecessary RVp. Ventricular autocapture also ensures beat-by-beat verification and adjusts the capture threshold to the lowest effective output. In-clinic time can be reduced by selecting the automated method instead of the manual method for retrieving device measurements.

Disclosure

The study was sponsored by St. Jude Medical.

Conflict of interest

All authors declare no conflict of interest related to this study.

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None.

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